

Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL05-013

June 8, 2005

Item: Guidant Model 1861 Ventak Prizm 2 DR, Implantable Cardioverter-Defibrillators (ICD) manufactured before November 2002

General Information: Guidant Corporation submitted voluntary advice to physicians, by letter on May 23, 2005, about an unpredictable breach of an insulator in the device. This insulator defect could result in at least partial diversion of current in the high-voltage output circuitry, thereby preventing the device from delivering high-voltage shock therapy when ventricular tachycardia or fibrillation is detected. This random component failure can occur in any Model 1861 ICD manufactured before November 13, 2002.

Specific Incident: Guidant reported that there have been 26 cases exhibiting the above failure mode from 37,000 devices implanted worldwide. In one of those cases, the patient may have died when the device failed to deliver high-voltage shock therapy.

Actions: 1. Within two weeks, electrophysiology/cardiology staff or other appropriate parties must identify all affected patients by implementing each of the following steps a through d. **It is important that ALL INFORMATION sources be reviewed to insure that patients will not be missed, as they may be found on one list and not on another.**

a) Review the manufacturer's letter (attached).

b) Review the patient list posted on the VA National ICD Surveillance Center intranet website (<https://icd.sanfrancisco.med.va.gov>). This list, provided by Guidant, consists of all the VA patients in the company's database that have an implanted model 1861 ICD which had been manufactured prior to November 13, 2002 and VA patients having this implant that are being followed at a VA facility.

c) Review the VA National registry for ICD implants Washington VAMC, point of contact is Ronald.Jones1@va.gov.

d) Review your patient records for all patients with implanted Guidant model 1861 Ventak Prizm 2 DR, ICD devices.

2. Within the next 45 calendar days, interrogate all Guidant Model 1861 ICDs for "no telemetry" or "warning screen" conditions. These conditions indicate that the ICD may be inoperative. If one of these conditions is present, replace with a suitable new device.

a) If the interrogation of the Guidant model 1861 ICD does not reveal a problem, the patient should be followed at the manufacturer's recommended intervals of every 3 months. However patients should be instructed to return immediately for device interrogation following any shock delivery, and ICD replacement should be considered at that time.

3. Follow the actions contained in Attachment 2. This guidance was prepared by Dr. Edmund Keung of the VA National ICD Surveillance Center as the best course of action for your patients.

Additional Information: See Guidant website www.guidant.com

Source: Guidant Corporation.

Contact: Dr. Edmund Keung at VA National ICD Surveillance Center at (415) 221-4810 Extension 3182 Or
Mr. Bryanne Patalil at National Center for Patient Safety (NCPS) at (734) 930-5890



May 23, 2005

Subject: PRIZM 2 DR, Model 1861

Dear Doctor:

Foremost in your mind and ours is the safety and well being of your patients. As a result of recent communications from sources other than Guidant regarding the VENTAK PRIZM® 2 DR ICD, we want to provide clarity and assure you that clinical performance of Guidant's PRIZM 2 DR ICD continues to exceed design expectations and ranks overall as one of the most reliable ICD products available.

Despite 20 years of progress and continuous quality improvement, ICDs remain subject to a range of rare and unpredictable failure modes often referred to collectively as "random component failures", some of which can result in inability to provide therapy. Identification and mitigation of failure modes such as these are direct outcomes of the Guidant Cardiac Rhythm Management Quality System. Our Quality System identified and mitigated one such failure mode in PRIZM 2 DR ICDs in 2002. After examination of two returned products, engineering analysis revealed that a rare and unpredictable breach in an insulator could result in at least partial diversion of current in the high-voltage output circuitry. Manufacturing and design enhancements were made to mitigate this rare and unpredictable event. The post-mitigation population has not exhibited this rare failure mode.

Clinical performance of Guidant's PRIZM 2 DR ICDs, in both the pre- and post-mitigation device populations, exceeds design expectations. The survival of the two populations is not statistically different because the rate of this failure in the pre-mitigation population is stable and very low at 0.002% per service month.

There have been 26 occurrences in the pre-mitigation population of approximately 37,000 devices implanted worldwide, 25 resulting in device replacement. In the latest reported event in March of this year, a device from this population was returned after a patient death and was found to have experienced this failure in conjunction with attempted delivery of at least one high-voltage therapy. All events have been reported to the appropriate regulatory bodies.

Guidant recommends that physicians continue normal monitoring for all patients with PRIZM 2 DR ICDs. As indicated in device labeling, all ICD patients should be monitored once per quarter. With reliability among the best in the industry, early replacement of pre-mitigation devices would likely not provide the patient with any lower risk of failure and would expose the patient to the risks of an invasive procedure. Guidant does not recommend replacement of these devices prior to the normal elective replacement indicators.

As a leading manufacturer of lifesaving technology, we take seriously our responsibility to create the most reliable products and services, enhance patient outcomes, and limit adverse events to patients. In addition to public regulatory reporting and periodic product performance publications, we will continue to undertake further specific physician communication to either improve patient outcomes related to device behavior or, as is the case here, limit potential adverse events resultant from potential confusion. If you have any questions regarding this communication, please contact your local Guidant representative or Guidant Technical Services at 1-800-CARDIAC (1-800-227-3422).

Sincerely,

A handwritten signature in black ink that reads "Allan Gorsett".

Allan Gorsett
Vice President, Reliability and Quality Assurance
Guidant Cardiac Rhythm Management

Guidant Corporation
4100 Hamline Avenue North
St. Paul, MN 55112-5798
Tel 651.582.4000 Fax 651.582.4166
www.guidant.com



DEPARTMENT OF VETERANS AFFAIRS

Medical Center
4150 Clement Street
San Francisco CA 94121

VA National ICD Surveillance Center

June 1, 2005

Dear colleagues:

This document is to provide you with more technical information on the issue involving the Guidant Model 1861 Ventak Prizm 2 DR ICD performance.

(A) The Problem:

- The ICD can fail to deliver shock of any magnitude when it detects ventricular tachy arrhythmias (VT or VF). The occurrence is **random**.

In order for the problem to occur, the following 4 events have to occur:

1. The wire (which acts as the negative pole) has to position close enough to the tube in the header that is filled with the inert gas (which is the positive pole)
 2. There has to be a breach of insulation on the wire
 3. There has to be a variation in the adhesive that is between the tube and the wire
 4. The shock has to jump from the negative pole to the positive pole to short out the can
- The problem does not occur during cap reform. Normal cap reform does not have predictive value.
 - The history of the ICD performance has no predictive value. A device can provide successful shock yesterday and fail to deliver shock today when VT/VF are detected. Similarly, doing a successful defibrillation test has no predictive value.
 - The bottom line: There is no way to predict which device will have this problem. Routine follow-up will not disclose the problem. The only way to find out is when the patient needs a therapeutic shock (and it fails)!

(B) Try to identify as many affected patients as possible. There are several sources:

- (1) The list of your affected patients that has been provided by your local Guidant representative.
- (2) Bryanne Patail, the biomedical engineer for the VA National Center for Patient Safety obtained a list of 225 patients from Guidant. These patients had either a model 1861 ICD manufactured prior to November 13, 2002 implanted or are being followed at a VA facility. You can go to the VA National ICD Surveillance Center website (<https://icd.sanfrancisco.med.va.gov>) to search for your own patients. **Please remember, this list is not complete. There are likely to be patients who are being followed in your clinics and not on this list.**
- (3) Washington DC VAMC maintains a national registry for ICD implants. Mr. Ron Jones can help you with your search. Ronald.Jones1@va.gov
- (4) Your own local database. This is the best, if you have one.

(C) What to do?

Guidant does not recommend replacement of the devices. We have to weigh the incidence and consequence of battery failure against potential complications with generator replacement. The

incidence of circuitry failure is low, at 1 in 2000 (0.05% or 0.002% per service month). However, if it fails, the result can be catastrophic for the patient. In patients with a history of frequent shock therapy or who are totally pacemaker-dependant, device replacement may be considered. We have to evaluate individual patient's clinical conditions, discuss the situation with the patients and arrive at the best course of action.

Ed Keung, MD
Ph: 415-221-4810, extension 3182
Edmund.Keung@med.va.gov

Instructions on how to access the VA National ICD Surveillance center database.

Perform the following steps to access your patient list supplied by Guidant on the VA National ICD Surveillance Center:

1. VA intranet URL: <https://icd.sanfrancisco.med.va.gov>
2. You have to register as a user first. Len Roberts, our administrator (Leonard.Roberts@med.va.gov) will review the information you provided and grant you access within 24 hours or less
3. After you log in, click on <Queries & Reports> and <Patient DeviceSearch>.
4. Select ICD Generator from the Filter by Device Type dropdown list.
5. Select Guidant from the Filter by Manufacturer drop-down list.
6. Enter "1861" in the Search Model textbox.
7. Click Go

You will see a list of all your patients with the affected devices. The device alert status is listed in the far right corner under the column heading Alert (Y=Yes). Do not forget that there may be more than one page for the list, depending on how many patients you have. You can export the table to an Excel spreadsheet or just print it.

You will notice that almost all your patients have SSN (social security number) and phone numbers of 888-88-8888 and (415) 221-4810, respectively. Guidant did not include the patients' SSN and phone numbers in their list. The medical centers listed under the column VAMC are the hospitals where they had their device implanted or the follow-up clinics, according to Guidant's records.

Status: R=registration only

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Alert

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Patient Device Search

Paging [Off] Filter by Status Device Type Filter by Manufacturer Search Patient Name

Items/page Filter by Implant Date From: To: Search Model Contains Starts with

Total records this view: 328 Total pages: 17 [Export to Excel] [Printer-friendly Version]

Patient	SSN	Status	Phone number	VAMC	Implant Date	Manufacturer	Model	Serial	Alert
Allen, Donald	888-88-8888	R	(415)221-4810	VA-Louisville	Jun 14 2002	Guidant	1861 Ventak Prism 2 DR	231388	Y
Agarwal, Joseph D	888-88-8888	R	(415)221-4810	VA-Tampa	Oct 8 2002	Guidant	1861 Ventak Prism 2 DR	240118	Y
Akers, Ronnie	888-88-8888	R	(415)221-4810	VA-ColumbiaMO	Jul 31 2001	Guidant	1861 Ventak Prism 2 DR	205876	Y
Alford, Walter	888-88-8888	R	(415)221-4810	VA-West LA	Feb 2 2001	Guidant	1861 Ventak Prism 2 DR	204887	Y
Arreola, Jose	888-88-8888	R	(415)221-4810	VA-San Antonio	Sep 13 2002	Guidant	1861 Ventak Prism 2 DR	230863	Y
Anderson, Andrew	888-88-8888	R	(415)221-4810	VA-Decatur	Jan 16 2003	Guidant	1861 Ventak Prism 2 DR	242256	Y
Archer, William	888-88-8888	R	(415)221-4810	VA-Gainesville	Jan 9 2002	Guidant	1861 Ventak Prism 2 DR	217911	Y
Armstrong, Eric	888-88-8888	R	(415)221-4810	VA-New York	Mar 11 2002	Guidant	1861 Ventak Prism 2 DR	217838	Y
Arrows, William C	888-88-8888	R	(415)221-4810	VA-Salt Lake City	Dec 8 2000	Guidant	1861 Ventak Prism 2 DR	200286	Y



June 01, 2005
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 Edmund Keung
 P/W exp 90 days

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